

## Food and Drug Administration, HHS

## § 520.1802b

(b) *Sponsors*. See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer 2 mg/kg of body weight twice daily.

(2) *Indications for use*. For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 15961, Mar. 19, 2012]

### § 520.1780 Pimobendan.

(a) *Specifications*. Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use*. For the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a case-by-case basis.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27733, May 17, 2007, as amended at 79 FR 18158, Apr. 1, 2014]

### § 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

#### § 520.1802a Piperazine-carbon disulfide complex suspension.

(a) *Specifications*. Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Horses and ponies*—(1) *Amount*. One fluid ounce per 100 pounds of body weight.<sup>1</sup>

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongylus* spp.), and pinworms (*Oxyuris equi*).<sup>1</sup>

(3) *Limitations*. Administer by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours. Provide water as usual. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics and other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[45 FR 52781, Aug. 8, 1980]

#### § 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications*. Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses and ponies*—(1) *Amount*. For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.<sup>1</sup>

(2) *Indications for use*. For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).<sup>1</sup>

(3) *Limitations*. Withhold feed overnight or for 8 to 10 hours. Give water

<sup>1</sup>These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

## § 520.1802c

just before and/or after treatment. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics or other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.<sup>1</sup>

[45 FR 52782, Aug. 8, 1980]

### § 520.1802c Piperazine-carbon disulfide complex with phenothiazine suspension.

(a) *Specifications.* Each fluid ounce contains 5 grams of piperazine-carbon disulfide complex and 0.83 gram of phenothiazine.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses and ponies—*(1) *Amount.* One fluid ounce per 100 pounds of body weight.

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), bots (*Gastrophilus* spp.), small strongyles, and large strongyles (*Strongylus* spp.).

(3) *Limitations.* See § 520.1802a(c)(3).

[45 FR 52782, Aug. 8, 1980]

### § 520.1803 Piperazine citrate capsules.

(a) *Specifications.* Piperazine citrate capsules contain piperazine citrate equivalent to 140 milligrams of piperazine base in each capsule.

(b) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in dogs and cats for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*).

(2) The contents of 1 capsule should be mixed with the food of the animal for each 5 pounds, or fraction thereof of body weight, except dogs weighing over 25 pounds should be given the contents of 6 capsules. The drug should be mixed in ½ of the regular feeding and when

## 21 CFR Ch. I (4–1–14 Edition)

the animal has finished eating the dosed food, the remainder of the food may be given. Dogs and cats may be wormed at 6 to 8 weeks of age. The first treatment should be repeated 10 days later. Reinfection may occur. Repeat treatment if indicated.

(3) Severely debilitated animals should not be wormed except on the advice of a veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 54 FR 38515, Sept. 19, 1989]

### § 520.1804 Piperazine phosphate capsules.

(a) *Specifications.* Each capsule contains 120, 300, or 600 milligrams of piperazine phosphate monohydrate.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* 60 milligrams of piperazine phosphate monohydrate per pound of body weight.<sup>1</sup>

(2) *Indications for use—*(i) *Dogs.* It is used for the removal of large roundworms (ascarids) *Toxocara canis* and *Toxascaris leonina*.<sup>1</sup>

(ii) *Cats.* It is used for the removal of large roundworms (ascarids) *Toxocara mystax* and *Toxocaris leonina*.<sup>1</sup>

(3) *Limitations.* Administer in animal's food or milk. For animals up to 1 year of age administer every 2 or 3 months; for animals over 1 year old, administer periodically as necessary. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.<sup>1</sup>

[43 FR 6941, Feb. 17, 1978; 43 FR 9804, Mar. 10, 1978, as amended at 46 FR 20158, Apr. 3, 1981; 69 FR 31878, June 8, 2004]

### § 520.1805 Piperazine phosphate with thenium closylate tablets.

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate) or 500 milligrams piperazine hexahydrate (as

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.